Exhibit(s) 100

Page(s) 313A thru 329A referred to:

U.S. Environmental Protection Agency Headquarters 1200 Pennsylvania Avenue NW Washington, DC 20004 The Agency has determined that all uses of methomyl, labeled and used as specified in this Reregistration Eligibility Decision document, are eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for methomyl. Where labeling revisions are imposed, specific language is set forth in Section V. of this document.

1. Food Quality Protection Act Findings

Determination of Safety for U.S. Population

The Agency has determined that established tolerances with amendments and changes as specified in this document for methomyl meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination the Agency has considered the available information on aggregate exposures, both acute and chronic, from food and water as well as the possibility of aggregate effects from methomyl and thiodicarb since thiodicarb degrades rapidly to methomyl.

Since there are no residential or lawn uses of methomyl, no dermal or inhalation exposure is expected in and around the home.

The results of the acute aggregate exposure analyses for food, for thiodicarb and methomyl, demonstrate that there are adequate margins of exposure for the general U.S. population (MOE=912). Estimated acute water exposures do not exceed the drinking water level of concern.

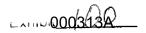
Results of the chronic aggregate exposure analyses for food, for thiodicarb and methomyl, show that for the general U.S. population, only 1.9% of the RfD is occupied. Estimated chronic water exposures do not exceed the drinking water level of concern.

Determination of Safety for Infants and Children

The Agency has determined that established tolerances with amendments and changes as specified in this document for methomyl meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for infants and children. In reaching this determination the Agency has considered the available information on the aggregate exposures, both acute and chronic, from food and water as well as the possibility of aggregate exposure from methomyl and thiodicarb since thiodicarb degrades rapidly to methomyl.

In determining whether to retain, reduce, or remove the 10x FQPA safety factor for infants and children, EPA uses a weight of evidence approach taking into account the





completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and information on exposure.

For purposes of assessing the pre- and post-natal toxicity of methomyl, EPA has evaluated two developmental studies and one reproduction study. Based on current toxicological data requirements, the data base for methomyl, relative to pre- and post-natal toxicity is complete. The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methomyl. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity. There was no assessment of potential susceptibility in the area of functional development.

There are however, data gaps for acute and subchronic neurotoxicity studies in rats. These studies are considered data gaps because methomyl has exhibited neurotoxic signs in two species (dogs and rabbits) by two different routes of exposure (oral and dermal). The Agency has determined that the need for a developmental neurotoxicity study should be placed in reserve status pending receipt and review of the acute and subchronic neurotoxicity studies.

Based on these considerations, the 10x Safety Factor for increased susceptibility to infants and children (as required by FQPA) was reduced to 3x.

The results of the acute aggregate exposure analyses for food, for thiodicarb and methomyl, demonstrate that there are adequate margins of exposure for children 1 to 6 years of age (MOE=417) and infants (MOE=756). Estimated acute water exposures do not exceed the drinking water level of concern.

Results of the chronic aggregate exposure analyses for food, for thiodicarb and methomyl, show that the most significantly exposed subpopulation is infants (<1 year old) with 6.5% of the RfD occupied. For children 1-6 years old, 2.7% of the RfD is occupied. Estimated chronic water exposures do not exceed the drinking water level of concern.

In deciding to continue to make reregistration determinations during FQPA implementation, the Agency recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these case-by-case decisions, the Agency does not intend broad precedents for the application of FQPA to its regulatory determinations. Rather, these first decisions will be made on a case-by-case basis and will not bind the Agency as it proceeds with further policy development and rulemaking that may be required.

If the Agency determines, as a result of this later implementation process, that any determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

102

FOR OFFICIAL USE ONLY Law Enforcement Sensitive

000314A Exhibit____

Endocrine Disruption

The Agency is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...". The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, the Agency may require further testing of this active ingredient and end use products for endocrine disrupter effects.

Cumulative Risk

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides for which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

The Agency does not have, at this time, available data to determine whether methomyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, The Agency has not assumed that methomyl has a common mechanism of toxicity with other substances.

2. Tolerance Reassessment

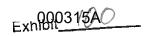
Tolerance Reassessment Summary

As a result of FQPA, pesticide residues are no longer regulated under section 409 of FFDCA. Consequently, all tolerances will eventually be placed in 40 CFR section 180. However, because methomyl tolerances still exist under sections 185 and 186, references to these sections are still used in this document. The Agency will issue a Federal Register Notice moving all methomyl tolerances listed under sections 185 and 186 to 40 CFR §180.253.

Tolerances for residues of methomyl in/on plant RACs are currently expressed in terms of methomyl [40 CFR §180.253 (a) and (b)]. A food/feed additive tolerance has been established for residues of methomyl in dried hops [40 CFR §185.4100].

A summary of the methomyl tolerance reassessment and recommended modifications in commodity definitions are presented in Table 50.

103



Tolerances Listed Under 40 CFR §180.253(a):

Sufficient data are available to ascertain the adequacy of the established tolerances on all listed commodities except for dry beans, bermudagrass forage, lentils, sorghum forage, and turnips (greens).

Additional residue data and/or label amendments are required before the adequacy of tolerances can be determined on bermudagrass forage, sorghum forage, radishes, and turnips (greens); and supporting storage stability data are required before tolerances can be reassessed on dry beans and lentils. Because the use on lentils is similar to the proposed use on dry peas, data on dried pea seeds will be translated to support the tolerance on lentils. Provided acceptable storage stability data are submitted, residue data on dry peas indicate that the tolerance on lentils should be increased to 0.2 ppm.

Tolerances on barley forage, bean forage, peanut hulls, and rye hay will be revoked because the Agency no longer considers these commodities to be significant livestock feed items due to revisions in Table 2. (Table 1 in OPPTS Guideline 860.1000).

In accordance with 40 CFR §180.1 (h), the tolerance on green onions covers leeks and the tolerance on peaches covers nectarines. Therefore, individual tolerances on leeks and nectarines will be revoked.

Tolerances will also be revoked for the outdated listings on leafy vegetables (exc. beet tops, broccoli, . . . etc.) and root crop vegetables. Tolerances either already exist for individual members of these outdated crop groups or sufficient data are available to establish new tolerances. In addition, the tolerance on Brassica (cole) leafy vegetables should be revoked because individual tolerances ranging from 2 to 6 ppm have been established on all brassica vegetables having registered uses.

Individual tolerances have been established on peppers (2 ppm) and tomatoes (1 ppm), and the available data support a 0.2 ppm tolerance in/on eggplants. Concomitant with establishing a tolerance on eggplant, the tolerance on fruiting vegetables must be revoked.

The available residue data on oranges, grapefruits, tangerines, and lemons adequately support a crop group tolerance for citrus fruits. Methomyl residues were <0.02-0.53 ppm in/on citrus fruits harvested 1 day following application(s) of methomyl at $\le 1x$ the maximum labeled rate. Therefore, a 1 ppm tolerance must be established on the citrus fruits crop group. Concomitant with establishing the crop group tolerance, individual tolerances for grapefruit, lemon, orange, and tangerines should be revoked.

Since there are no registered uses on watercress, the tolerance on watercress should be revoked.

104

Tolerances Listed Under 40 CFR §180.253 (b):

Sufficient data are available to ascertain the adequacy of the established 4 ppm tolerance with a regional registration on pears.

Tolerances Listed Under 40 CFR §185.4100:

Sufficient data are available to ascertain the adequacy of the established 12.0 ppm tolerance on imported dried hops. In accordance with PR Notice 93-12 (12/93), dried hops are now regulated as a RAC. A permanent tolerance will be established on dried hops cones, and the food additive tolerance will be revoked.

New Tolerances Needed Under 40 CFR §186.253 (a):

Sufficient data are available to determine appropriate tolerances for aspirated grain fractions (grain dust), the citrus fruits crop group, dried citrus pulp, cowpea forage, eggplant, dried hops cones, and sugar beet tops. Grain dust data generated using treated wheat and sorghum indicate that a 25 ppm tolerance is needed for methomyl residues in/on aspirated grain fractions. The available residue data support methomyl tolerances of 1 ppm in/on citrus fruits, 10 ppm in/on cowpea forage, 0.2 ppm in/on eggplants, 10 ppm in/on dried hops cones, and 2 ppm in/on sugar beet tops.

Before tolerances can be established on cowpea hay, bulb onions, pea seeds, field pea seeds and hay, root and tuber vegetables, sorghum stover and hay, and soybean hay, storage stability data are required to support the available residue data.

Provided the registrant submits acceptable storage stability data, the available residue data also support methomyl tolerances of 0.2 ppm on the root and tuber vegetables crop group, 0.2 ppm in/on onion bulbs, 0.2 ppm in/on pea seeds and field pea seeds, 2 ppm in/on field pea hay, 10 ppm in/on cowpea hay, 0.2 ppm in/on soybean hay, 4 ppm in/on sorghum stover, and 1 ppm in/on sorghum hay.

Tolerances are required for methomyl residues in/on chicory tops, radish tops, and cotton gin byproducts. Appropriate tolerances will be determined once residue data are submitted.

The following table provides a tolerance reassessment summary for methomyl.

105 **CUI**

000317A

Table 50 - Tolerance Reassessment Summary for Methomyl

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition	
Commodity				
.10.10		under 40 CFR §180.2		
Alfalfa	10	10	Separate tolerances each at 10 ppm should be established for alfalfa, forage and alfalfa, hay.	
Apples	1	1	Apple	
Asparagus	2	2		
Avocados	2	2	Avocado	
Barley, forage	10	Revoke	No longer considered to be a significant feed item.	
Barley, grain	1	1		
Barley, hay	10	10		
Barley, straw	10	10		
Beans, dry	0.1 (N)	0.1 ª	Storage stability data are required to support the reassessed tolerance. Bean, seed	
Beans, forage	10	Revoke	No longer a regulated feed item.	
Beans, succulent	2	2	Bean, succulent	
Beets, tops	6	6	Beets, tops (leaves)	
Blueberries	6	6	Blueberry	
Brassica (cole) leafy vegetables	6	Revoke	Individual tolerances ranging from 2 to 6 ppm have been established for brassica vegetables with registered uses.	
Broccoli	3	3		
Brussels sprouts	2	2		
Cabbage	5	5		
Cabbage, Chinese	5	5		
Cauliflower	2	2		
Celery	3	3		
Citrus Fruits Crop Group	None	1	The available data support a 1 ppm tolerance for the Citrus Fruits Crop Group	
Collards	6	6		
Corn, fodder	10	10		
Corn, forage	10	10		
Corn, fresh (inc. sweet) (K+CWHR)	0.1 (N)	0.1	Corn, sweet (K+CWHR)	
Corn, grain (inc. pop)	0.1 (N)	0.1	Corn, grain	
Cottonseed	0.1 (N)	0.1	Cotton, seed, undelinted	
Cucurbits	0.2 (N)	0.2	Cucurbit Vegetables Crop Group	
Dandelions	6	6		
Endive (escarole)	5	5		



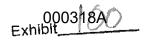


Table 50 (continued).

	Current Tolerance	Talamana	C. III	
Commodity	(ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition	
Grapefruit	2	Revoke	Tolerance should be revoked once a 1 ppm tolerance is established for the Citrus Fruits Crop Group.	
Grapes	5	5	Grape	
Grasses, Bermuda	10	TBD ^b	Additional data are required. Grass, Bermuda, forage	
Grasses, Bermuda, hay (dry, dehydrated)	40	40	Grass, Bermuda, hay	
Kale	6	6		
Leeks	3	Revoke	In accordance with 40 CFR §180.1 (h), residues in/on leeks are covered by the tolerance on green onions.	
Lemons	2	Revoke	Tolerance should be revoked once a 1 ppm tolerance is established for the Citrus Fruits Crop Group.	
Lentils	0.1	0.2 ^a	Once supporting storage stability data are provided for dried legume seeds, data on dry pea seed, which will be translated to support the use on lentils. These data indicate that the tolerance should be increased to 0.2 ppm. Lentil, seed.	
Lettuce	5	5		
Mint, hay	2	2	Separate tolerances each at 2 ppm should be established for peppermint, tops and spearmint, tops.	
Mustard, greens	6	6		
Nectarines	5	Revoke	In accordance with 40 CFR §180.1 (h), residues in/on nectarines are covered by the tolerance on peaches.	
Oats, forage	10	10		
Oats, grain	1	1		
Oats, hay	10	10		
Oats, straw	10	10		
Onion, green	3	3		
Oranges	2	Revoke	Tolerance should be revoked once a 1 ppm tolerance is established for the Citrus Fruits Crop Group.	
Parsley	6	6		
Peaches	5	5	Peach	

107 **CUI**

FOR OFFICIAL USE ONLY Law Enforcement Sensitive

000319**()** Exhibit_____

Table 50 (continued).

Commedia	Current Tolerance	Tolerance	Comment/Correct Commodity	
Commodity	(ppm)	Reassessment (ppm)	Definition	
Peanuts	0.1 (N)	0.1	Peanut, nutmeat	
Peanuts, hulls	0.1 (N)	Revoke	No longer a regulated feed item.	
Peas	5	5	Pea, succulent	
Peas, vines	10	10	Vines of pea cultivars used for human food are no longer considered to be a significant feed item; only vines of field pea cultivars grown for livestock feeding are regulated. The current tolerance should be changed to Pea, field, vines.	
Pecans	0.1	0.1	Pecan	
Peppers	2	2	Pepper, bell and non-bell	
Pomegranates	0.2 (N)	0.2		
Rye, forage	10	10		
Rye, grain	1	I		
Rye, hay	10	Revoke	No longer considered to be a significant feed item.	
Rye, straw	10	10		
Sorghum, forage	1	TBD	A label amendment or additional data are required.	
Sorghum, grain	0.2 (N)	0.2		
Soybeans	0.2 (N)	0.2	Soybean, seed	
Soybean, forage	10	10		
Spinach	6	6		
Strawberries	2	2	Strawberry	
Swiss chard	6	6	350,750,750	
Tangerines	2	Revoke	Tolerance should be revoked once a 1 ppm tolerance is established for the Citrus fruits Crop Group.	
Tomatoes	1	1	Tomato	
Turnips, greens, tops	6	TBD	Additional data are required unless the registrnat removes turnip greens, tops from the federal labels.	
Vegetables, fruiting	0.2 (N)	Revoke	Tolerance should be revoked once a 0.2 ppm tolerance is established for <i>Eggplants</i> . Separate tolerances are already established on tomatoes and peppers.	

Table 50 (continued).

	Current Tolerance	Tolerance	Comment/Correct Commodity
Commodity	(ppm)	Reassessment (ppm)	Definition
Vegetables, leafy (exc. beets(tops), broccoli, Brussels sprouts, cabbage, cauliflower, celery, Chinese cabbage, collards, dandelions, endive (escarole), kale, lettuce, mustard greens, parsley, spinach, Swiss chard, turnip greens (tops), and watercress)	0.2 (N)	Revoke	The outdated tolerance for leafy vegetables should be revoked because separate tolerances have been established for leafy vegetables commodities with registered uses.
Vegetables, root crop	0.2 (N)	Revoke	The outdated tolerance for root crop vegetables should be revoked once a tolerance is established for the Root and Tuber Vegetables Crop Group
Watercress	6	Revoke	There are no registered uses on watercress.
Wheat, forage	10	10	
Wheat, grain	1	1	
Wheat, hay	10	10	
Wheat, straw	10	10	
Tolerances w	ith A Regional Regi	stration listed under 4	0 CFR §180.253 (b):
Pears	4	4	Pear
Food	Additive Tolerance	s listed under 40 CFR	
Hops, dried	12	Revoke	In accordance with PR Notice 93-12 (12/93), dried hops are now regulated as a RAC. A section 408 tolerance should be established on <i>Hops cones, dried</i> .
	Tolerances needed	under 40 CFR §186.2	53 (a):
Aspirated grain fractions	None	25	The available data indicate that a 25 ppm tolerance should be proposed for Aspirated grain fractions.
Chicory, tops (leaves)	None	TBD	Additional data are required.
Citrus, pulp, dried	None	2	The available data indicate that the registrant should propose a 2 ppm tolerance for Citrus pulp, dried.
Cotton gin byproducts	None	TBD	Data are required.

Table 50 (continued).

	Current Tolerance	Tolerance	Comment/Correct Commodity	
Commodity	(ppm)	Reassessment (ppm)	Definition	
Cowpea, forage	None	10	Cowpea is the only bean foliage crop the Agency considers to be a significant livestock feed item. The available bean forage and hay	
Cowpea, hay	None	10 °	data support equivalent tolerances on cowpea forage and hay. Tolerances should be proposed for Cowpea, forage and Cowpea, hay.	
Eggplant	0.2 °	0.2	The registrant should propose a 0.2 ppm tolerance for <i>Eggplant</i> .	
Onions, bulb	0.2 ^d	0.2 ^a	Once acceptable storage stability data are available, the registrant should propose a 0.2 ppm for Onions, bulb.	
Pea, seed	None	0.2 ª	Once acceptable storage stability data are available, the available data support the proposed tolerances.	
Pea, field, hay	None	2 ª	Once acceptable storage stability data are available, the registrant should propose tolerances for <i>Pea</i> ,	
Pea, field, seed	None	0.2 ^a	field, seed and Pea, field, hay, which are supported by the available dry pea data.	
Hops cones, dried	None	10	As per PR Notice 93-12 (12/93), a section 408 RAC tolerance should be established for <i>Hops cones</i> , <i>dried</i> . In addition, a review of the available residue data indicate that the import tolerance can be lowered to 10 ppm to achieve compatibility with the Codex MRL.	
Radish, tops (leaves)	None	TBD	Data are required.	
Root and Tuber Vegetables Crop Group	None	0.2 ª	Once supporting storage stability data are available for potato, adequate data will be available to support a crop group tolerance for the Root and Tuber Vegetables Crop Group	
Sorghum, stover	None	4 ª	Storage stability data are required to	
Sorghum, hay	None	1 8	support the proposed tolerances.	

Table 50 (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Soybean, hay	None	0.2 ^a	Based upon the proposed 12-day PHI, the available residue data support a 0.2 ppm tolerance. Once supporting storage stability data are available the registrant should propose a revised tolerance on Soybean, hay.
Sugar beet, tops	0.2 °	2	The available data indicate that the tolerance should be increased to 2 ppm. Beets, sugar, tops (leaves).

- ^a Reassessed tolerance is tentative pending submission of supporting storage stability data.
- b TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.
- ^c Tolerance as part of the outdated fruiting vegetables crop group.
- ^d Tolerance as part of the outdated root crop vegetables group.
- * Tolerance as part of the outdated leafy vegetables crop group.

Codex Harmonization

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for methomyl residues in/on various plant and animal commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Codex has combined MRLs for thiodicarb and methomyl into a single listing. Codex MRLs and U.S. tolerances are not presently compatible because the U.S. tolerance expression currently includes only methomyl, whereas the Codex MRL residue definition includes methomyl and methomyl oxime (methyl hydroxythioacetimidate).

A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table 51.

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs:

- "If the Codex MRL residue definition for methomyl is amended to include only methomyl, U.S. tolerances and Codex MRLs would be compatible for the following crops/commodities: alfalfa, asparagus, beans (dry and succulent), cabbage, cauliflower, citrus fruits, cucumbers, eggplants, grapes, hops, lettuce (head), melons, mint hay, onions (bulb), pea vines, peaches/nectarines, peanuts, peas (succulent), sorghum, soybeans, soybean forage, summer squashes, tomatoes, and watermelons. In addition, the MRL and tolerance for sorghum forage would be compatible if the registrant chooses to restrict the U.S. use to only grain sorghum.
- " Based upon the use patterns registered in the U.S. and the available residue data, compatibility of U.S. tolerances and Codex MRLs is not possible for the following

crops/commodities: celery, cottonseeds, kale, maize (field corn), oats, welsh onion, peppers, pome fruits, potato, spinach, sugar beet, sweet corn, and wheat.

Table 51 - Codex MRLs for methomyl and applicable U.S. tolerances.

Codex				
Commodity (As Defined)	MRL (mg/kg)	Step	Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Alfalfa forage (green)	10	CXL	10	
Asparagus	2	CXL	2	
Barley	0.5	CXL	1	IIC wasidua data indicata that higher
Barley straw and fodder, dry	5	CXL	10	U.S. residue data indicate that higher tolerances are required.
Beans (dry)	0.1	CXL	0.1	
Cabbages, head	5	CXL	5	
Cauliflower	2	CXL	2	
Celery	2	CXL	3	U.S. residue data indicate that the higher tolerance is required.
Citrus fruits	1	CXL	1	
Common bean (pods and/or immature seeds)	2	CXL	2	
Cotton seed a	0.5	CXL	0.1	U.S. residue data indicate that a lower tolerance is acceptable.
Cucumber	0.2	CXL	0.2	Covered by U.S. tolerance for the Cucurbit Vegetables Crop Group.
Egg plant	0.2	CXL	0.2	
Grapes	5	CXL	5	
Hops, dry	10	CXL	10	
Kale	5	CXL	6	U.S. residue data indicate that the higher tolerance is required.
Lettuce, head	5	CXL	5	
Maize ^a	0.05 * ^b	CXL	0.1	U.S. residue data indicate that the higher tolerance is required.
Maize fodder a	50 fresh wt.	CXL	10	U.S. residue data indicate that a lower
Maize forage ^a	50 fresh wt.	CXL	10	tolerance is acceptable.
Meat (from mammals other than marine mammals)	0.02 *	CXL	None	The Agency has determined that residues in meat represent a 40 CFR §180.6(a)(3) situation; therefore U.S. tolerances are not required.

Codex				
Commodity (As Defined)	MRL (mg/kg)	Step	Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Sorghum forage (green)	1	CXL	TBD °	Additional residue data are required to support the U.S. tolerance, or the current 1.0 ppm tolerance could be compatible if the registrant restricts the use to only grain sorghum.
Soya bean (dry) *	0.2	CXL		U.S. tolerance for soybeans does not
Soya bean (immature bean)	0.1	CXL	0.2	distinguish between immature and mature seeds.
Soya bean forage (green)	10	CXL	10	
Spinach	5	CXL	6	U.S. residue data indicate that a higher tolerance is required.
Squash, summer	0,2	CXL	0.2	Covered by U.S. tolerance for the Cucurbit Vegetables Crop Group.
Sugar beet	0.1	CXL	0.2	Covered by U.S. tolerance for the Root and Tuber Vegetables Crop Group; U.S. residue data indicate that a higher tolerance is required.
Sweet corn (corn-on- the-cob) *	2	CXL	0.1	U.S. residue data indicate that a lower tolerance is acceptable.
Tomato *	1	CXL	1	
Watermelon	0.2	CXL	0.2	Covered by U.S. tolerance for the Cucurbit Vegetables Crop Group
Wheat	0.5	CXL	1	U.S. residue data indicate that a higher tolerance is required.
Wheat straw and fodder, dry	5	CXL	10	

- * MRL is based upon thiodicarb use.
- An asterisk (*) signifies that the MRL was established at or about the limit of detection.
- To be determined; additional residue data are required.

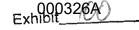
3. Summary of Risk Management Decisions

Human Health

The Agency concludes that there are no acute dietary concerns associated with potential residues of methomyl from application of thiodicarb and methomyl in food. Based on Monte Carlo analysis with the level of concern being an MOE of 300, sufficient margins of exposure exist [U.S. population (MOE=912), children 1 to 6 years of age (MOE=417) and

Table 51 (continued).

Codex	AND THE PROPERTY OF THE PROPER	A STATE OF THE STA		
Commodity (As Defined)	MRL (mg/kg)	Step	Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Melons, except watermelon	0.2	CXL	0.2	Covered by U.S. tolerance for the Cucurbit Vegetables Crop Group
Milks	0.02 *	CXL	None	The Agency has determined that residues in milk represent a 40 CFR §180.6(a)(3) situation; therefore a U.S. tolerance is not required.
Mint hay	2	CXL	2	
Nectarine	5	CXL	None	Covered by 5.0 ppm U.S. tolerance on peaches.
Oat straw and fodder, dry	5	CXL	10	U.S. residue data indicate that the higher tolerance is required.
Oats	0.5	CXL	1	U.S. residue data indicate that the higher tolerance is required.
Onion, bulb	0.2	CXL	0.2	
Onion, Welsh	0.5	CXL	3	Covered by U.S. tolerance for green onions; U.S. residue data indicate that a higher tolerance is required.
Pea vines (green)	10	CXL	10	
Peach	5	CXL	5	
Peanut	0.1	CXL	0.1	
Peanut forage (green)	5	CXL	None	U.S. label directions prohibit feeding of treated peanut vines to livestock.
Peas (pods and succulent—immature seeds)	5	CXL	5	Succulent podded and shelled peas are covered
Peas, shelled (succulent)	0.5	CXL	-	by a single U.S. tolerance.
Peppers	1	CXL	2	U.S. residue data indicate that a higher tolerance is required.
Pineapple	0.2	CXL	None	Not registered for this use in the U.S.
Pome fruits	2	CXL	None	Separate U.S. tolerances have been established for apples at 1.0 ppm and pears at 4.0 ppm
Potato	0.1	CXL	0.2	Cover by U.S. tolerance for the Root and Tuber Vegetables Crop Group; U.S. residue data indicate that a higher tolerance is required.
Sorghum	0.2	CXL	0.2	



infants (MOE=756)] at the high-end percentile exposure level of interest (99.9th percentile value).

Results of the chronic exposure analysis show that no single subpopulation exceeded 7% of the RfD. For the subpopulations, non-nursing infants (<1 year old) and children (ages 1-6 years old), 6.5% and 2.7% of the RfD is occupied, respectively. For the general U.S. population, only 1.9% of the RfD was occupied.

Estimated concentrations of methomyl in surface and ground water are less than the Agency's levels of concern for methomyl in drinking water as a contribution to acute and chronic aggregate exposure. Therefore, the Agency concludes that aggregate exposure to all sources of methomyl does not exceed the Agency's risk concerns.

To minimize the risks of potential systemic toxicity to mixers/loaders the Agency is requiring the use of personal protective equipment and/or the use of engineering controls (water soluble bags).

Environmental Fate and Effects

Laboratory studies indicate that methomyl is moderately persistent and highly mobile. It is stable to hydrolysis at lower pH's (neutral to acidic) and degrades slowly in alkaline conditions. Methomyl photolyzes quickly in water but more slowly in soils. It is moderately stable to aerobic soil metabolism but degrades more rapidly under anaerobic conditions. In laboratory studies, methomyl does not readily adsorb to soil and has the potential to be very mobile. Field studies show varying dissipation rates of the chemical in soils. Dissipation rates were related primarily to differences in soil moisture content, which may affect the microbial activity, and rainfall/irrigation, which could influence leaching.

Methomyl has been detected in ground water in a prospective ground water monitoring study and in other reported incidences. While it may reach ground water under certain conditions, methomyl will not likely persist under many conditions. Methomyl can contaminate surface water as a result of spray drift during application or by runoff from treated sites. Methomyl would not be expected to persist in clear, shallow waters because of its susceptibility to photolysis.

The major concerns for non-target organisms are the chronic risks posed by the use of methomyl to non-target mammalian and freshwater invertebrate organisms. Risks to aquatic invertebrates from exposure to methomyl are likely to occur wherever methomyl is used. Accumulation of methomyl from repeated applications contributes to the chronic risks.

4. Ecological Risk Mitigation for Methomyl

To lessen ecological and potential water risks posed by methomyl, EPA is requiring the following mitigation from registrants of methomyl containing products.

115

1) The registrant will revise end use product labels to reduce the maximum seasonal use rates as noted in the table below;

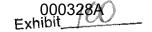
Table 52 Revised Maximum Seasonal Use Rates

Crop	From Present Season Rate (lb ai)	To New Season Rate (lb ai)	Percent Decrease
Broccoli	7.2	6.3	12.5
Cabbage	9.0	7.2	20
Cauliflower	9.0	7.2	20
Celery	9.0	7.2	20
Chinese cabbage	8.1	7.2	11.1
Corn, sweet	7.2	6.3	12.5
Lettuce, head	9.0	7.2	20
Tomato	7.2	6.3	12.5

These measures will result in less loading of methomyl in the environment.

- 2) The registrant will reduce the single maximum per acre application rate of methomyl by 50% from 1.8 pounds to 0.9 pounds on peaches and commercial sod farms. No methomyl crop use will exceed a single application rate of 0.9 pounds of methomyl per acre.
- 3) The following statement supporting the use of an Integrated Pest Management (IPM) plan must be added to the labels.
 - "This product should be used as part of an Integrated Pest Management (IPM) program which can include biological, cultural, and genetic practices aimed at preventing economic pest damage. Application of this product should be based on IPM principles and practices including field scouting or other detection methods, correct target pest identification, population monitoring and treating when target pest populations reach locally determined action thresholds. Consult your state cooperative extension service, professional consultant or other qualified authorities to determine appropriate action threshold levels for treating specific pest/crop systems in your area."
- 4) Based on the environmental risk assessment for methomyl, the following advisories are required to be on the label for methomyl: a labeling statement for potential ground water contamination, a labeling statement to minimize the potential for surface water contamination and labeling statements are required on manufacturing use products and end use products based on the toxicity to nontarget organisms. A bee hazard statement is also required.





5) The following spray drift label requirement for products with aerial applications is required to be on the label for methomyl: "Do not apply by ground equipment within 25 feet, or by air within 100 feet of lakes, reservoirs, rivers, estuaries, commercial fish ponds and natural, permanent streams, marshes or natural, permanent ponds. Increase the buffer zone to 450 feet from the above aquatic areas when ultra low volume application is made."

5. Restricted Use Classification

Based on its acute toxicity and use patterns, the Agency is maintaining Restricted Use classification for all methomyl products that are currently so classified.

6. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures to address the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

7. Labeling Rationale

At this time, all products containing methomyl are intended primarily for occupational use (e.g. mixed, loaded, and applied by occupational applicators only; generally not available to homeowners). No registered use is likely to involve applications at residential sites.

The Worker Protection Standard (WPS)

The Agency has issued the Worker Protection Standard for Agricultural Pesticides (WPS) affecting all pesticide products whose labeling reasonably permits use in the commercial or research production of agricultural plants on any farm, forest, nursery, or greenhouse. In general, WPS products had to bear WPS-complying labeling when sold or distributed after April 21, 1994. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted entry intervals (REI), and notification were interim. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes.

At this time some of the registered uses of methomyl are within the scope of the WPS and some uses are outside the WPS scope.